In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 25, 2024

MICHAEL J. SAYLES,	*	
	*	Special Master Sanders
Petitioner,	*	
v.	*	No. 20-1817V
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Brian Robert Arnold, Brian R. Arnold & Associates, Richardson, TX, for Petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON MOTION TO DISMISS[1]

On December 2, 2020, Michael J. Sayles ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Pet., ECF No. 1. Petitioner filed an amended petition on May 12, 2022, alleging that the administration of the influenza ("flu") vaccine he received on January 10, 2020, caused him to "suffer[] an onset of shoulder injury and/or an acute complication of sequella [sic] of an illness, disability, injury, or condition." Am. Pet. at 4, ECF No. 43. Petitioner alleged his injury as a Table claim with a presumption of causation, and in the alternative, "an aggravation of a medical condition as the result of vaccine." *Id.*

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has not met his legal burden.

[1]Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act," "the Act," or "the Program"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek*

Petitioner has not provided preponderant evidence that he suffered from a shoulder injury related to vaccine administration ("SIRVA"), nor has he provided preponderant evidence that the flu vaccine he received on January 10, 2020, is the "sole direct and proximate cause of [his] injuries, or the cause of aggravation of a medical injury." *Id.* For the reasons set forth below, I find that Petitioner is not entitled to compensation, and his claim should be dismissed.

I. Procedural History

The initial, handwritten petition, filed pro se by Petitioner on December 2, 2020, alleged that he suffered from swelling, pain, and bruising at the vaccination site. Pet. at 1. On May 17, 2021, Petitioner obtained counsel who filed a motion to substitute as counsel. ECF No. 14. Petitioner requested several extensions of time due to difficulties obtaining his complete medical record. ECF Nos. 16, 20–21. On October 8, 2021, Petitioner filed motions to issue subpoenas to two medical providers. ECF Nos. 24–25. An affidavit from Petitioner, a declaration from a treating nurse, and medical records were filed on December 8, 2021. Pet'r's Exs. 1–5, ECF Nos. 29–31. Additional medical records were filed on February 28, 2022. Pet'r's Ex. 6, ECF No. 34. On March 10, 2021, Petitioner filed photographs depicting his alleged injuries. Pet'r's Exs. 7a–7d, ECF No. 35. The following day, March 11, 2021, Petitioner's counsel filed an affidavit detailing the difficulties he had in attempting to obtain Petitioner's medical records. ECF No. 36. He noted his intention to continue collection procedures. *Id.* Notices of intent to file on portable storage were filed on March 14 and 15, 2022, and the Clerk's office received the disc/drive on March 18, 2022. ECF Nos. 37–38, Pet'r's Ex. 8. Petitioner filed additional medical records on March 29, and April 1, 2022. Pet'r's Exs. 10–11, ECF Nos. 39–40. Medical records were again filed on May 12, 2022, along with Petitioner's amended petition, and a statement of completion. Pet'r's Ex. 12, Am. Pet., ECF Nos. 42–44.

Respondent filed a motion to dismiss and a Rule 4(c) report on December 9, 2022. Resp't's Mot., ECF No. 46. Petitioner responded on February 13, 2023. Pet'r's Resp., ECF No. 48. This matter is ripe for a decision on entitlement.

II. Summary of the Relevant Evidence

a. Medical Records

i. Hospitalization/Vaccination

Petitioner received his flu vaccination on January 10, 2020, during a hospitalization for chest pain and dizziness. Pet'r's Ex. 3 at 28, 95, ECF No. 30. He was sixty-nine years old and residing at a nursing home facility at the time. *Id.* at 28. The vaccine was administered in his left deltoid. *Id.* at 95.

Petitioner immediately complained of left shoulder pain post vaccination and continued to complain throughout his hospitalization. *Id.* at 71, 173, 186, 194. Petitioner told medical personnel that he had a previous rotator cuff tear and had experienced a fall two weeks prior to the

v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

hospitalization with resulting soreness. *Id*. at 71. He reported the pain as "exponentially worse on January 11, 2020, and examination of his left posterior deltoid revealed that his shoulder was "swollen, indurated, and with rubor attributable to heat pack." *Id.* The examination record also noted hypertonicity, tenderness, and passive limited range of motion. *Id.* Petitioner's treaters considered tendonitis rupture secondary to fall or intravenous treatment vs. subdeltoid bursitis secondary to vaccination vs. an acute infection or less likely, Reiter's syndrome. *Id.*

Petitioner continued to report left shoulder pain on January 13 and 14, 2020. *Id.* at 186, 194. During an occupational therapy evaluation on January 14, 2020, Petitioner reported that he had been self-treating his left upper shoulder for severe pain brought on by a flu vaccination. *Id.* at 242. That same day, Petitioner was discharged to Senior Care of Harbor Lakes ("Harbor Lakes"), a skilled nursing facility. *Id.* at 251–53. Upon arrival at Harbor Lakes, Petitioner was examined by Carrie Lauderdale, registered nurse ("RN"), who noted his decreased range of motion in his left shoulder. Pet'r's Ex. 8 at 3171.

ii. Post Vaccination

Harbor Lakes records dated February 25, 2020, detail Petitioner's medical history at the time of admission. *Id.* at 4. His primary diagnosis was unspecified chronic obstructive pulmonary disease with an onset date of January 14, 2020. *Id.* Other conditions, symptoms, and complaints included right and left knee pain, weakness, gait and mobility abnormality, and essential hypertension. *Id.* at 7.

On March 2, 2020, Petitioner was examined by Randall Barnes, D.O. Pet'r's Ex. 4 at 12, ECF No. 31-1. Petitioner included the flu vaccine when reporting his allergies. *Id.* Petitioner also reported arthritis in the weight bearing joints, back pain, and noted that he was currently seeing a urologist for a urologic workup. *Id.* at 12–13. On April 29, 2020, about three months post vaccination, Petitioner complained to Harbor Lakes nurse practitioner ("NP"), Robin Conner, that both his elbows were "sore with fluid sacs." *Id.* at 10. Upon examination, Petitioner's elbows were sore to palpation and appeared red and warm with fluid sacs. *Id.* NP Conner diagnosed Petitioner with bilateral olecranon bursitis, prescribed an antibiotic, and referred Petitioner to orthopedics. *Id.* During therapy the following day, Petitioner appeared to have full range of motion and no significant loss of strength, despite swelling and pain in his elbows. Pet'r's Ex. 8 at 2717, 3147.

Approximately two months later, on May 7, 2020, Petitioner presented to Cody Hartshorn, M.D., at Lakeside Physicians Orthopedics, with a two-week history of bilateral elbow pain and swelling. Pet'r's Ex. 5 at 9–14, ECF No. 31-2. Petitioner reported numbness, tingling, weakened grip in his left hand, and dull aching in the elbow, which radiated up the arm toward the shoulder. *Id.* at 10. X-ray imaging of the right elbow revealed mild degenerative changes and calcification of the lateral epicondyle. *Id.* at 14. X-ray imaging of the left elbow showed a small spur around the olecranon with soft tissue calcifications and swelling. *Id.* Dr. Hartshorn diagnosed Petitioner with "spontaneous onset" bilateral olecranon bursitis and recommended wrapping the elbows in compression bandages for about two weeks. *Id.* at 10.

On June 25, 2020, about five months post vaccination, Petitioner was seen again by NP Conner during general rounds at his skilled nursing facility. Pet'r's Ex. 4 at 9. Petitioner reported

that he "d[id] not really have any complaints." *Id.* NP Conner noted that Petitioner had a history of bilateral elbow pain from bursitis and a drainage procedure performed by Dr. Hartshorn. *Id.* From October 5 to October 11, 2020, Petitioner repeatedly complained of right elbow pain. Pet'r's Ex. 8 at 1990–2010. He had bruising from his right elbow to his armpit and on his outer right arm from his elbow to his shoulder. *Id.* at 1999. X-ray imaging performed on October 8, 2020, showed no fracture. *Id.* at 1996. Petitioner was started on an antibiotic and a Medrol Dosepak. *Id.* at 2001.

NP Connor saw Petitioner again on February 3, 2021. *Id.* at 8. He reported no complaints or issues with his extremities since having his elbows drained. *Id.* On April 29, 2021, NP Conner noted that Petitioner was "always complaining of pain, always wanting something else, but it seem[ed] like his pain [was] really under control." *Id.* at 7. A medical record dated August 28, 2021, indicated that Petitioner had been prescribed Tylenol with Codeine for complaints of pain in his back and shoulder. Pet'r's Ex. 8 at 1297.

b. Petitioner's Affidavit

In his affidavit, Petitioner described his vaccination as immediately painful. Pet'r's Ex. 1 at 1, ECF No. 29-1. He stated that his "arm immediately started swelling and burning with much pain." *Id.* Petitioner described how the nurse removed the needle from the original vaccination site in his left arm and finished it in his right arm. *Id.* He remembered it was the same arm as his pick line and stated that the injection in his right arm was also "very painful." *Id.* Following his vaccination, both of Petitioner's arms "reacted violently" at the injection sites. *Id.* at 2. Petitioner described his injuries as "on again, off again," and noted that his prostate surgery had to be cancelled because of the bilateral swelling in his arms. *Id.* His "right arm had swollen to the point of bursting," and after "it did," he developed "a big yellowish/black and blue bruise." *Id.* at 2–3. As of May 25, 2021, the date of his affidavit, Petitioner reported that he was "still experiencing pain and swelling at times." *Id.* at 5.

c. Sworn Statement of Alice Schluter

Ms. Schluter is a nurse at the Harbor Lakes Senior Care Facility. Pet'r's Ex. 2 at 1, ECF No. 29-2. She noted that Petitioner had complained of arm pain, and she saw that his right hand had "noticeable swelling" with "a small bump on his right elbow." *Id.* A few days later, Ms. Schluter noticed that Petitioner "had purple bruising starting on his right arm[, and t]he bump on his elbow had grown to slightly larger than a golf ball." *Id.* His left arm and elbow displayed the "same effects" during this same time. *Id.*

d. Photographs

Petitioner filed four, undated photographs of what appear to be arms. Pet'r's Exs. 7a–7d, ECF No. 35. The first photograph depicts an arm with extensive redness and bruising alongside a bump by the elbow. Pet'r's Ex. 7a. The second photograph shows an arm with extensive redness and blue/black bruising across the interior of the elbow and upper arm along the bicep. Pet'r's Ex. 7b. The subject is wearing a tee-shirt that covers the shoulder. *Id.* The third photograph is also of an upper arm from a different angle. Pet'r's Ex. 7c. The bruising appears the entire length of the upper, inner arm towards the armpit, but it is then obscured by a tee-shirt. *Id.* The last photograph

depicts a complete arm, and the shirt has been removed. Pet'r's Ex. 7d. The bruising spans from just about the wrist on the inside of the arm, up through the elbow and into the inner, upper arm. *Id.* There does not appear to be any bruising on the shoulder. *Id.*

III. Motion to Dismiss

a. Respondent's Motion

Respondent filed his Rule 4(c) report within his motion to dismiss. He describes Petitioner's claim as a SIRVA and acknowledges that "[t]he medical record evidence indicates that [P]etitioner experienced left shoulder pain and limited range of motion through January 14, 2020, for a period of only four days post-vaccination." Resp't's Mot. at 6. To the extent that Petitioner did complain of left-sided pain after the initial four days post vaccination, Respondent argues "the pain was attributed to his left elbow." *Id.* Respondent then notes that the right elbow and arm bruising evidence that was submitted is "irrelevant to potential vaccine placement." *Id.* at 5 n.5. Likewise, Respondent notes that Petitioner's self-described photographs also depict his right side. *Id.* Respondent succinctly continues that the current record contains "no evidence to support a finding that [P]etitioner suffered the residual effects or complications of a left-sided SIRVA for more than six months after administration of his flu vaccine." *Id.* at 6. Without an injury that lasted six months or resulted in inpatient hospitalization and surgical intervention, Petitioner "has not satisfied the requirements of 42 U.S.C. § 300aa-11(c)(1)(D)." *Id.* at 7. Respondent submitted no additional filings.

b. Petitioner's Response

Petitioner's characterization of his injury differs significantly from Respondent. Petitioner notes that "[b]oth arms from the shoulder down reacted violently with painful swelling and bruising." Pet'r's Resp. at 1–2. Petitioner also describes "overall weakness, loss of muscle strength, pain in his shoulders and body injury." *Id.* Although Petitioner asserts a shoulder injury as a result of his flu vaccine, he also argues that "he developed weakness and numbness in his arms." *Id.* at 6. Petitioner's argument for why he is entitled to award of damages is also brief and consists of one paragraph. *Id.* at 5. He references his medical record and asserts that he "has suffered the residual effects of complications of such illness, disability, injury, or condition for more than [six] months after the administration of the vaccine he received on or about January 10, 2020 and continues to do so." *Id.* Petitioner states that he "will require future medical care and therefore, Respondent's motion to dismiss should be denied." *Id.* Petitioner submitted no additional evidence.

IV. Applicable Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that he suffered a "Table" injury-i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); § 13(a)(1)(B).

The Vaccine Injury Table lists a SIRVA as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 14(a) as amended by 42 CFR § 100.3. Table injury cases are guided by statutory qualifications and aids to interpretation ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. *See* 42 CFR § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . .. A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;[4]
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if a petitioner is unable to establish a Table claim, he may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table," or causation-in-fact, claim requires that a petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 13(a)(1)(A); *see* § 11(c)(1)(C)(ii)(II). A petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citations omitted).

[4] Pain onset within 48 hours in a necessary condition for SIRVA injuries. 42 C.F.R. § 100.3(c)(10)(ii).

In the seminal case of *Althen v. Sec'y of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is also unnecessary. *Althen*, 418 F.3d at 1278–81; *Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id.* at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data

and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See* 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Id.* at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that [the] vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . .." *Capizzano*, 440 F.3d at 1325-26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* (quoting *Althen*, 418 F.3d at 1280). In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685

F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403-04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

The Vaccine Act requires a petitioner to present a claim for compensation for a "vaccine-related injury or death," as well as preponderant evidence supporting her claim. § 300aa-11(c); § 300aa-13(a)(1)(A); *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47, 56 (2014), *aff'd*, 607 F. App'x 997 (Fed. Cir. 2015). Accordingly, a petitioner must specify her "vaccine-related injury and shoulder the burden of proof on causation." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). Where the identity and nature of the vaccine-related injury is in dispute, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1352-53 (Fed. Cir. 2011). However, "the function of a special master is not to 'diagnose' vaccine-related injuries." *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009). Instead, the special master must determine, "based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury." *Id.* (quoting *Knudsen*, 35 F.3d at 549.

In Table and off-Table claims, a petitioner must show by preponderant evidence that he "suffered the residual effects or complications of such illness, disability, injury, or condition for more than [six] months after the administration of the vaccine."[5] 42 U.S.C. § 300aa-11(c)(1)(D)(i); *see Song v. Sec'y of Health & Hum. Servs.*, 31 Fed. Cl. 61, 65-66 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). Finding that a petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not look only to medical records. *See* § 13(a)(1); *see Colon v. Sec'y of Health & Human Servs.*, 156 Fed. Cl. 534, 541 (2021). Special masters may consider the whole record in evaluating whether there is preponderant evidence for the severity requirement and may find the severity requirement satisfied even if a petitioner's medical records for the alleged injury is not continuous for the six months following the injury. *See Kirby*, 997 F.3d 1378.

[5] Petitioner can also meet the duration requirement with a preponderant showing that death resulted from the vaccine, or that the "illness, disability, injury, or condition [] resulted in inpatient hospitalization and surgical intervention." 42 U.S.C. § 300aa-11(c)(1)(D). There is no evidence or assertion from Petitioner that either of these alternative showings are applicable in this case.

V. Analysis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the *Althen* analysis. *Broekelschen*, 618 F.3d at 1346. Since Table applicability and/or "each prong of the *Althen* test is decided relative to the injury[,]" determining facts relating to the claimed injury can be significant. *Id.* Here, Petitioner's amended petition declared it "evident that [Petitioner] sustained a Table Injury as a result of the [flu] vaccine he received as defined in the [Table]; shoulder injury related to vaccine administration." Am. Pet. at 4. As such, Petitioner has to establish by preponderant evidence that his claim meets the QAI criteria for a Table SIRVA, in addition to duration and severity requirements for all Program claims. Petitioner's Table claim fails because even assuming that he could have developed SIRVA in both shoulders due to his vaccine administration starting in one shoulder and moving to the other, his pain and reduced range of motion are not limited to his shoulder(s). Petitioner complained of pain "in his shoulder and *body generally*." *Id.* at 3. (emphasis added). Petitioner also complained of elbow swelling, pain, and bruising. He described the pain as dull aching in the elbow, which radiated up the arm toward the shoulder. Elbow injury is not a characteristic of SIRVA. Furthermore, it is preponderant evidence of another condition or abnormality that would explain his symptoms. Because Petitioner is unable to meet these two QAI Table requirements, Petitioner must establish but-for causation for his injury.

Petitioner's amended petition also included general language of an off-Table claim. He stated that he "suffered a shoulder injury and/or an acute complication or sequella [sic] of an illness, disability, injury, or condition." *Id.* at 4. Petitioner alleged, "in the alternative[, he] suffered an aggravation of a medical condition." *Id.* Petitioner does not, in his petition or response to Respondent's motion to dismiss, name such illness, disability, injury, or condition, or identify the acute complications of such. He does not explain which of his symptoms are properly characterized as sequela of SIRVA. He does not identify a pre-existing condition that could have been significantly aggravated by his vaccination. He does not explain how such condition was worsened by his flu vaccine. Additionally, he does not offer evidence that could be used to apply to the factors considered in a significant aggravation claim.[6] Without identifying or defining the nature of Petitioner's injury, Petitioner has not provided a basis for a causation theory connecting the flu vaccine to said injury.

The difficulties in comprehensively analyzing Petitioner's case are compounded as I move through the factors. Petitioner has not presented preponderant evidence of a Table SIRVA or identified another recognizable injury. He also has not presented preponderant evidence that meets the duration and severity requirements for his shoulder injury. There is significant evidence that Petitioner suffered from an adverse reaction following his vaccination. His medical records document complaints of pain and swelling. Additionally, Petitioner had decreased range of motion in January of 2020. Petitioner's treater identified post-vaccination bursitis as a differential diagnosis for the shoulder pain. However, during monthly examinations conducted at Harbor Lakes from February through June of 2020, Petitioner did not complain of shoulder pain or any

[6] The *Loving* case outlines what a petitioner must establish for entitlement in a significant aggravation claim. Although Petitioner noted significant aggravation as a potential alternative theory, he provided no evidence to support such a claim. Therefore, I have not included the applicable standard outlined in *Loving.*

other symptom that is consistent with a shoulder injury related to vaccine. The symptoms that clearly illustrate a shoulder injury during Petitioner's January 10–14, 2020 hospitalization were no longer mentioned by Petitioner in February and beyond. When asked during his examinations at Harbor Lakes, Petitioner offered no additional complaints beyond his elbow pain and pre-existing conditions. Without additional complaints, treatment, test results, or contextual evidence from Petitioner of six months of shoulder pain, Petitioner does not present preponderant evidence that his shoulder injury lasted beyond January of 2020.

Petitioner's remaining evidence focused on his elbow injury. Although his elbow injury continued for longer than six months, Petitioner alleged in his amended petition that he suffered a shoulder injury related to vaccine administration. Am. Pet. at 4. The steady complaints, examinations, and treater's opinions that detail bruising, swelling, and bilateral elbow pain are inconsistent with SIRVA, and Petitioner never linked these symptoms to his shoulder or the vaccine. Even his submitted photographs do not depict shoulder bruising, swelling, or other injury that could provide circumstantial evidence of a vaccine-caused injury.

The Federal Circuit has made it clear that there is no specific type of evidence that is required for a claim to be successful. Indeed, in Table cases, medical records are sufficient to establish a presumption of entitlement and ultimately lead to an award of damages. Because this case does not meet the requirements for a Table SIRVA, Petitioner is required to prove his case with preponderant evidence of causation. Medical records, expert reports, affidavits from treaters or laypersons, medical literature, vaccine inserts, VAERS reports, case reports, small- and large-scale studies, and photographs, are examples of the types of evidence frequently seen in the Program's off-Table cases. There is not, however, a one-size-fits-all approach to success. Petitioner must provide preponderant evidence of vaccination, injury, and duration of injury. Petitioner must also provide preponderant evidence to satisfy the *Althen* prongs, specifically (1) a sound and reliable medical theory connecting the vaccine to the injury; (2) a logical sequence of cause and effect; (3) and an appropriate temporal relationship between the vaccination and injury. After a comprehensive review of the entire record, Petitioner has not provided preponderant evidence of the foundation of his claim, namely the nature or duration of his injury. Furthermore, Petitioner has not provided preponderant evidence to meet prong one of *Althen*, and the record does not provide sufficient evidence to conduct a meaningful *Althen* prong two analysis. There is no causation theory to apply to the facts of this case. Petitioner was given an opportunity to respond to Respondent's assertions that he did not satisfy the six-month duration requirement. He noted that he was treated for the swelling and bruising in his arms and cited to elbow pain and swelling detailed in his medical records. He also stated that he "continued to suffer from injury and residual effects, disability and complications for more than six months," without any additional details. Pet'r's Resp. at 3. He did not request to obtain an expert or provide any literature to articulate the basis for a but-for causation claim. Petitioner has not provided preponderant evidence to meet prong two of *Althen.*

Petitioner has provided preponderant evidence that he suffered a shoulder injury within 48 hours of his flu vaccine. His medical records clearly establish that the pain he sustained post vaccination was immediate and severe. He continued to complain of shoulder pain in the days that followed, and medical providers noted redness, swelling, and limited range of motion. Furthermore, although Petitioner does not present a causation theory for his shoulder injury,

SIRVA is a well understood mechanism in the program and can be established through medical records in some cases. In this case, however, Petitioner's medical records clearly shift in focus from shoulder pain to elbow pain upon his discharge from the hospital, four days post vaccination. While this temporal relationship between Petitioner's shoulder injury and his flu vaccination does satisfy *Althen* prong three, the general severity and duration requirement is not met. Moreover, Petitioner does not allege that he suffered an elbow injury or provide causation evidence for a vaccine-caused elbow injury that identifies an appropriate temporal relationship for that injury following vaccination.

VI. Conclusion

After careful review of the record, Petitioner has not established by preponderant evidence that he suffered from a Table SIRVA, an off-Table shoulder injury, or any other condition that was caused-in-fact by his January 10, 2020 flu vaccination. Accordingly, Petitioner is not entitled to compensation and this case must be dismissed.

IT IS SO ORDERED.

/s/ Herbrina D. Sanders
Herbrina D. Sanders
Special Master